Claim status

Claims 1-7 and 9-14 are pending in this case. Claims 1-7 and 9-14 stand rejected.

Non-statutory provisional double patenting rejection

Claims 1, 2, 4, 7 and 11 stand rejected on judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claim 30 of U.S. Patent No. 7,001,920 and Claim 41 of U.S. Patent No. 6,673,838.

Without addressing the merit of the rejection, in order to facilitate the prosecution of the current case, Applicants acknowledge that a terminal disclaimer may be used to overcome a rejection on judicially created doctrine of obviousness-type double patenting upon a finding that all other rejections have been overcome.

Claim rejections under 35 U.S.C. § 112, first paragraph

Claims 1-7 and 9-14 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. It is alleged in the Office Action that Applicants have not shown that the presently disclosed compounds are all antidepressants.

Applicants respectfully traverse the rejection under 35 U.S.C. § 112, first paragraph.

To satisfy the written description requirement under 35 U.S.C § 112, first paragraph, the specification should contain a written description of the invention and the manner and process of making and of using it, in such a way, to enable the person of ordinary skill in the art to practice the invention without undue experimentation.

Applicants respectfully maintain that one skilled in the art, with Applicants disclosure before him or her, would be able to practice the claimed invention without undue experimentation.

The present application incorporates by reference, U.S. Patent No. 4,535,186 (Husbands *et al.*), which discloses (see column 1) that the compounds of the presently claimed formula, substituted phenethylamine derivatives, are central nervous system antidepressants.

As acknowledged in the Office Action, the present specification does teach a method of treating obesity by administering venlafaxine. As described in the present specification (page 8, lines 21-24), the administered dosages of venlafaxine were well within the dosage range prescribed for the use of venlafaxine to treat depression.

It is known in the art that antidepressants treat bulimia. For example Pope *et al.* (cited in the Office Action dated April 1, 2009) teach the use of a variety of antidepressants for the treatment of bulimia.

In view of the above, Applicants submit that the presently claimed invention clearly satisfies the written description requirement and respectfully request the withdrawal of the rejection of claims 1-7 and 9-14 under 35 U.S.C. § 112, first paragraph.

Claim rejections under 35 U.S.C. § 103

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Freeman *et al.* (Int. J. Obs., 1987, p 171-7) (hereinafter "Freeman *et al.*") and Walsh (J. of Psychosomatic Research, 1991, p 33-40) (hereinafter "Walsh") in view of Fabre *et al.* (Curr Therapeutics Res, 42, 5, 1987) (hereinafter "Fabre *et al.*").

The Office Action states Freeman *et al.* and Walsh teach the benefits of fluoxetine, which is an antidepressant and a serotonin reuptake inhibitor, in a method of treating bulimia nervosa. Further the Office Action states that one of ordinary skill in the art would have been motivated to administer venlafaxine for another antidepressant and a serotonin reuptake inhibitor such as fluoxetine in a method for treating bulimia.

Applicants respectfully traverse the rejections under 35 U.S.C. § 103(a).

Freeman *et al.* disclose the results "of a small study using fluoxetine in the treatment of bulimia nervosa". Based on these results the authors conclude that "fluoxetine may have a role in the treatment of bulimia nervosa and that further investigation is warranted." (first paragraph page 171) In conclusion Freeman *et al.* state in their last paragraph "It is not possible to state from this small study whether fluoxitine is acting because of its antidepressant, anti-anxiety or specific anti-bulimic properties."

Freeman *et al.* also describe the use of a number of known antidepressants from a variety of drug classes for the treatment of bulimia, including tricyclic antidepressants (imipramine, amitriptyline), or monoamine oxidase inhibitors (phenelzine) or dopamine reuptake inhibitors (nomifensine). Freeman et al. report a study which indicated that mianserin, a serotonin reuptake inhibitor had no effect. Therefore, one would not assume that venlafaxine would treat bulimia nervosa.

Walsh specifically refers to fluoxetine, known as an antidepressant, known to block neuronal serotonin reuptake, for the treatment of bulimia nervosa. Walsh refers to Freeman *et al.* open study, double-blind, placebo-controlled trial and to a study conducted in the United States and Canada in 13 centers, where two doses of fluoxetine and placebo were compared.

Walsh comes to the conclusion that the use of fluoxetine is associated with significant symptomatic improvement, in same time important issues related to the use of fluoxetine for bulimia nervosa remain unsolved, bringing up the question whether fluoxetine is the first-choice medication for bulimia nervosa and if there is any danger in the long-term use of this drug.

Walsh also brings up the question of "how treatment with fluoxetine compares to non-pharmacological forms of therapy for bulimia nervosa" and when antidepressant medication should be started in the treatment process compared to psychotherapy.

However, unlike the claimed compound, venlafaxine, none of the drugs discussed in Freeman *et al.* and Walsh, are combined norepinephrine and serotonin uptake inhibitors (SNRIs). Since the presently claimed method defines the administration of compounds neither taught nor suggested by Freeman *et al.* and Walsh for the treatment of bulimia, the references provide no reasonable expectation of success for the claimed method. The conclusions stated by Freeman *et al.* as well as by Walsh do not motivate one skilled in the art to administer an antidepressant other than fluoxetine in a method for treating bulimia, nor do they provide reasonable expectation of success.

Fabre *et al.* refer to both enantiomers of venlafaxine and state in their first paragraph of page 902 "in general the results of animal studies suggest that this new compound may have antidepressant activity in humans". Fabre *et al.* teach a preliminary assessment of compound Wy-45,030 clinical tolerance and pharmacokinetic properties in healthy men. Fabre *et al.* conclude that "Further testing is indicated to determine the drug's efficacy in treating depression". Fabre *et al.* do not disclose the use of Wy-45,030 in a method for treating bulimia nervosa. The teachings of Fabre *et al.* do not overcome the deficiencies of Freeman *et al.* and Walsh.

Based on Freeman et al, Walsh and Fabre *et al.* one of ordinary skilled in the art would have no motivation or reasonable expectation of success in using venlafaxine for treating bulimia nervosa or in using the enantiomers of venlafaxine for this purpose.

In view of the foregoing, Applicants maintain that claims 1-7 are not rendered obvious in light of Freeman *et al.* and Walsh, in view of Fabre *et al.* and respectfully request that the rejection be withdrawn.

Claims 1-5, 7 and 9-14 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Freeman *et al.* and Walsh, in view of Edgren *et al.* (US 6,440,457) (hereinafter "Edgren *et al.*"). Applicants respectfully traverse this rejection.

Edgren *et al.* teach a method for administering venlafaxine, to the gastrointestinal tract of a human, over an extended period of time in a therapeutically responsive dose to produce antidepressant therapy. Edgren *et al.* teach an osmotic pump form of venlafaxine.
Edgren *et al.* do not teach a method of treating a human suffering from bulimia nervosa with venlafaxine.

The Office Action states that one having ordinary skill in the art at the time of the invention, based on Freeman *et al.* and Walsh's teachings, would have been motivated to administer venlafaxine, in a method of treatment of bulimia, and expect to achieve similar or superior therapeutic benefits compared to fuoxetine. As argued above, these references do not provide motivation or expectation of success in using venlafaxine for this purpose.

The teachings of Edgren *et al.* do not overcome the deficiencies of Freeman *et al.* and Walsh. In view of the foregoing, Applicants maintain that claims 1-5, 7 and 9-14 are not rendered obvious in light of Freeman *et al.* and Walsh, in view of Edgen *et al.* and respectfully request that the rejection be withdrawn.
Nothing in Edgren *et al.* would motivate the person of ordinary skill in the art to administer venlafaxine for the treatment of bulimia, and as stated above, Freeman *et al.* and Walsh do not teach or suggest the use of the claimed compounds for treating bulimia.

Claim 6 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Freeman *et al.* and Walsh in view of Edgren *et al.* as applied to claims 1-5, 7 and 9-14 and further in view of Fabre *et al.*
Applicants respectfully traverse this rejection.

Claim 6 defines the localized positions of substituents R_5 and R_6 on the phenyl ring relative to the point of attachment and does not relate to stereoselectivity.
The Office Action states that it would have been obvious for the person of skill in the art to prepare and separate selective stereoisomers of venlafaxine for its use in treating bulimia nervosa.
Applicants apply their above statements with regards to Freeman *et al.*, Walsh, Edgren *et al.* and Fabre *et al.*
None of these compounds cited in Fabre *et al.* have substituents at the meta position. Fabre *et al.* do not teach or suggest the use of venlafaxine stereoisomers in the treatment of bulimia nervosa.

Therefore there is no motivation in separating the enantiomers of venlafaxine and using them in the treatment of bulimia nervosa.

In view of the above, Applicants respectfully request the withdrawal of the rejection of claim 6 under 35 U.S.C. § 103(a) over Freeman *et al.* and Walsh in view of Edgren *et al.* and further in view of Fabre *et al.*

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

For all the foregoing reasons, it is respectfully requested that the panel find that all existing claims are in condition for allowance and that the application should pass to issue, or that there is allowable subject matter in the claims and that prosecution on the merits should be reopened.

If a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at 973 660 6088.

Respectfully submitted,

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